MAY 23 2002

510(k) Summary

K020587

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

Submitter of this premarket notification	Pulsion Medical Systems, AG C/O James M. Delaney EXPERTech Associates, Inc. 100 Main Street, Ste 120 Concord, MA 01742 Phone 978.371.0066 Fax 978.371.1676 e-mail: jdelaney@fdahelp.com
Date of summary	January 29, 2002
Device name	Pulsion Pulsiocath PiCCO Monitoring Kit, Injectate Sensor Temperature Housing PV 4046
Common name	Injectate in-line sensor

Classification names

Regulation Number	Classification Name
§870.1915	Probe, Thermodilution

Predicate Devices: The modified device is substantially equivalent to the device previously cleared under K991886.

Modifications: The primary modifications are changes to the injectate in-line sensor design, materials, and dimensions. Corresponding dimensional changes have been made to the housing to accommodate additional components and their positioning within the housing resulting from the change.

Intended Use: The modified device has the same intended use as previously cleared in K991886. The PV4046 injectate in-line sensor is a component of a prescription use accessory package to the Pulsion PiCCO Cardiac Output System. The accessory package was cleared with the following Indications for Use:

The PULSION Pulsiocath Thermodilution Catheter and Pressure Monitoring Kit with Injectate In-Line Sensor are intended for use with the PULSION PiCCO Cardiac Output System for the measurement of cardiac output by the thermodilution method, measurement of arterial blood pressure, and for cardiac output determination by arterial pulse contour analysis. The PULSION PiCCO Cardiac Output System with Thermodilution Catheter and Pressure Monitoring Kit with Injectate In-Line Sensor is indicated in patients where cardiovascular and circulatory volume status monitoring is necessary. Such as patients in surgical, medical, cardiac, and burn specialty units as well as other specialty units where cardiovascular monitoring is desired and patients undergoing surgical

	interventions of such magnitude that cardiovascular monitoring is necessary.
Technological characteristics	The modified device has the same technological characteristics as the legally marketed predicate devices.
Testing	Verification and validation testing activities were conducted to establish the performance and reliability characteristics of the modified device. Testing involved safety testing from the risk analysis, including laboratory studies for performance, mechanical properties, and biocompatibility. Acceptance criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2002

Pulsion Medical Systems, Inc.
c/o Mr. James M. Delaney
EXPERTECH Associates, Inc.
100 Main Street, Suite 120
Concord, MA 01742

Re: K020587
Pulsion Pulsiocath PiCCO
Regulation Number: 870.1915
Regulation Name: Thermodilution Probe
Regulatory Class: Class II (two)
Product Code: 74 KRB
Dated: February 19, 2002
Received: February 22, 2002

Dear Mr. Delaney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

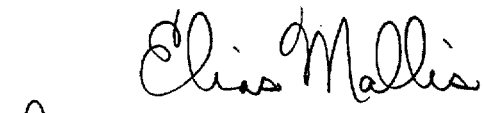
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.1 ODE Indications Statement

Indications for Use Statement

510(k) Number (if known) K020587

Device Name

The Pulsion PV4046 Injectate Sensor component of the PULSION Pulsiocath Thermodilution Catheter and Pressure Monitoring Kit with Injectate In-Line Sensor

Indications for Use

The PULSION Pulsiocath Thermodilution Catheter and Pressure Monitoring Kit with Injectate In-Line Sensor are intended for use with the PULSION PiCCO Cardiac Output System for the measurement of cardiac output by the thermodilution method, measurement of arterial blood pressure, and for cardiac output determination by arterial pulse contour analysis. The PULSION PiCCO Cardiac Output System with Thermodilution Catheter and Pressure Monitoring Kit with Injectate In-Line Sensor is indicated in patients where cardiovascular and circulatory volume status monitoring is necessary. Such as patients in surgical, medical, cardiac, and burn specialty units as well as other specialty units where cardiovascular monitoring is desired and patients undergoing surgical interventions of such magnitude that cardiovascular monitoring is necessary.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elias Mallis

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K020587

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)